IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

RAVGEN, INC., **Plaintiff,** **v.** **LABORATORY CORPORATION OF AMERICA HOLDINGS,** **Defendant.**	**Civil Action No. 6:20-cv-00969-ADA** **JURY TRIAL DEMANDED**

PLAINTIFF RAVGEN, INC.'S OPENING CLAIM CONSTRUCTION BRIEF

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INTRODUCTION

This patent infringement action involves technology for the preparation and/or analysis of cell-free nucleic acids, including in non-invasive prenatal testing as well as cancer-related applications. Plaintiff Ravgen Inc. ("Ravgen") owns fundamental patents relating to that technology, including U.S. Patent Nos. 7,332,277 ("the '277 Patent") and 7,727,720 ("the '720 Patent") (collectively, the "Patents-in-Suit"). Laboratory Corporation of America Holdings ("LabCorp" or "Defendant") commercialize genetic tests using cell-free DNA that include the patented methods.

As discussed below, Ravgen proposes that the disputed claim terms be given their plain and ordinary meaning in the art, as supported by the intrinsic record of the Patents-in-Suit. By contrast, for the disputed terms, LabCorp's proposed constructions depart from the ordinary meanings and the guidance in the intrinsic record, asking the Court to rewrite the claims to add extraneous limitations. Therefore, LabCorp's proposals should be rejected.

BACKGROUND

Ravgen incorporates by reference the background sections from *Ravgen, Inc. v. Natera, Inc.*, No. 1:20-cv-00692-ADA, Dkt. 46 at 1-3 (W.D. Tex. Dec. 15, 2020) ("*Natera* case") and *Ravgen, Inc. v. PerkinElmer, Inc.*, No. 1:20-cv-00822-ADA, Dkt. 50 at 1-3 (W.D. Tex. Dec. 4, 2020) ("*PerkinElmer* case").

DISPUTED TERMS

I. "determining the sequence of a locus of interest" ('277 Patent, Claim 55)

Ravgen's Proposed Construction	LabCorp's Proposed Construction
plain and ordinary meaning	determining the identity of one nucleotide or of contiguous nucleotides or nucleosides of a selected region of nucleic acid

This Court previously construed the term "determining the sequence of a locus of interest"

as used in Claim 55 of the '277 Patent to have its plain and ordinary meaning. *See PerkinElmer* case, Dkt. 78 at 2. Pursuant to the parties' agreement to forgo briefing on this term and rely on the prior briefing from the *PerkinElmer* case, Ravgen hereby incorporates by reference its claim construction briefing, including all exhibits, from that case. *See PerkinElmer* case, Dkts. 50, 53, 58. Ravgen reserves the right to respond to any arguments LabCorp raises in its Responsive brief.

II. "free . . . DNA" / "free . . . nucleic acid" ('277 Patent, Claims 55, 58, 81, 130; '720 Patent, Claims 1, 21)

Ravgen's Proposed Construction	LabCorp's Proposed Construction
plain and ordinary meaning	"extracellular, i.e., outside the cell . . . DNA" / "extracellular, i.e., outside the cell . . . nucleic acid"

"Free . . . DNA" and "free . . . nucleic acid" should be given their plain and ordinary meaning. The patentee did not act as its own lexicographer by clearly setting forth definitions of the phrases "free . . . DNA" and "free . . . nucleic acid" nor did the patentee disavow any scope of those phrases in the specification or during prosecution. *See Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). Therefore, these terms should be given their plain meaning.

During the parties' meet and confer, LabCorp asserted that its proposed construction for these terms is necessary to provide clarification for the jury. But that assertion is without merit. LabCorp's proposal takes the easily understood, four-letter term "free" and rewrites it as "extracellular, i.e., outside the cell." This proposal contains four words and an abbreviated Latin phrase, injecting unnecessary ambiguity and complexity for the Court and the jury.

To the extent LabCorp is asserting that the terms "free" and "extracellular" are synonyms or can be used interchangeably, that cannot justify rewriting these clear terms. *See C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862–63 (Fed. Cir. 2004) ("merely rephrasing or paraphrasing

the plain language of a claim by substituting synonyms does not represent genuine claim construction."). Indeed, the word "extracellular" does not appear in the claims or the specifications of the Patents-in-Suit. The Court should reject LabCorp's attempt to rewrite these claim terms to replace the clear language chosen by the patentee with LabCorp's preferred language.

LabCorp's identified extrinsic scientific articles do not support its proposed construction. In fact, the extrinsic evidence identified by LabCorp supports Ravgen's position that "free DNA" is a clear and well-understood term in the art. *See* LC-RAV00009723 (article titled "Free DNA in the Serum of Cancer Patients and the Effect of Therapy" using the term "free DNA" throughout the article); LC-RAV00009729 (using the term "free DNA" in the article); LC-RAV-00009735 (using the term "free fetal DNA" throughout the article); LC-RAV-00009739. The use of the terms "free DNA" and "free fetal DNA" in the extrinsic evidence supports that the term is clear and, therefore, does not require construction. *See Pisony v. Commando Constr., Inc.*, No. W-17-cv-00055-ADA, 2019 WL 928406, at *5 (W.D. Tex. Jan. 23, 2019) (where "there is nothing about the claim term that is confusing . . . the term requires no construction.").

III. "free fetal DNA isolated" / "isolating free fetal nucleic acid" / "isolating free nucleic acid" ('277 Patent, Claims 55, 81; '720 Patent, Claim 1) [1]

Ravgen's Proposed Construction	LabCorp's Proposed Construction
plain and ordinary meaning	"separate out free fetal DNA from everything else" / "separating out free fetal nucleic acid from everything else" / "separating out free nucleic acid from everything else"

LabCorp's proposed constructions unjustifiably deviate from the plain and ordinary meaning of the isolating terms in an attempt to impermissibly limit those terms and rewrite the

[1] These terms are referred to collectively herein as "the isolating terms."

claim language to the exclusion of every example provided in the specification.[2] Neither the intrinsic nor extrinsic record supports limiting the isolating terms as LabCorp proposes. LabCorp's proposal should thus be rejected, and the isolating terms given their plain and ordinary meaning.

A. The Isolating Terms Do Not Require Construction Because The Plain Language Is Clear.

The Patents-in-Suit do not explicitly define the isolating terms. And for an obvious reason: the isolating terms are clear. A person of ordinary skill in the art ("POSITA") would understand that the plain meaning of isolating nucleic acids encompasses well-known, standard techniques in the art to remove or reduce other components in a nucleic acid sample. *See* '277 Patent at 31:48–51 ("[a]ny standard DNA isolation technique can be used to isolate" free nucleic acids from a sample.); *see also id.* at 26:44–57; '720 Patent at 32:57–60. In addition to being clear, the patentee did not clearly disavow any scope of the isolating terms in the specification or during prosecution. *See, e.g.*, Ex. 3 at -00013016. Thus, the isolating terms should be given their plain and ordinary meaning. *See Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012).[3]

[2] The isolating terms were previously construed by this Court in the *Natera* case to have their plain and ordinary meaning. *See Natera* case, Dkt. 88 at 2. LabCorp's proposed constructions substantially overlap with Natera, Inc.'s proposed constructions in the Natera case. *Compare Natera* case, Dkt. 63 at 9 ("[t]he asserted claims themselves already require isolating fetal DNA from maternal DNA") *with* "separating out free fetal nucleic acid from everything else." Accordingly, the Court should give the isolating terms the same construction—their plain and ordinary meaning.

[3] LabCorp's extrinsic dictionary definitions of "isolate" do not warrant departing from the plain meaning. First, because the plain meaning of that word is clear on its face, the Court need not consider extrinsic evidence. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317–19 (Fed. Cir. 2005) (*en banc*). Moreover, the proffered dictionary definitions and scientific article do not support a definition of "isolating" that requires complete separation "from everything else" as LabCorp's proposed construction requires. Regardless, the dictionary definitions and scientific article are unrelated to the field of cell-free nucleic acids.

B. LabCorp's Proposed Construction Is Incorrect Because It Imports Additional Limitations And Excludes Every Example In The Specification.

LabCorp's proposed construction takes the clear terms "isolated" and "isolating" and rewrites those terms as "separate out from everything else" and "separating out from everything else." But these proposed constructions are incorrect because they import an additional limitation into the plain language and because they would exclude every example provided in the specification. *See Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1276–77 (Fed. Cir. 2008) ("[w]e normally do not interpret claim terms in a way that excludes embodiments disclosed in the specification").

LabCorp's proposals would improperly rewrite the clear, plain language of the isolating terms to import a new and unsupported requirement. For example, Claim 81 of the '277 Patent, which recites "isolating free fetal nucleic acid from the sample," [4] would, under LabCorp's construction, read: "~~**isolating**~~ **separating out** free fetal nucleic acid **from everything else** from the sample." First, LabCorp's proposals would improperly replace the patentees chosen term "isolating" with its own language "separating out." Second, while the plain language of the claims merely require that the methods comprise isolating free nucleic acid from other components of a sample (*e.g.*, blood or plasma), LabCorp's proposals attempt to limit the claims by requiring isolating the free nucleic acid from ***everything else*** in a sample. That new requirement finds no support in the plain language or the record.

Not only is this proposal in the context of the rest of the claim language cumbersome, but this limitation—that nucleic acid be separated from everything else in the sample—is inconsistent

[4] During the parties' meet and confer, LabCorp confirmed that the use of the words "a the sample" in Claim 81 of the '277 Patent was an obvious error and should be construed by the Court to mean "the sample," consistent with the Court's rulings in the *PerkinElmer* and *Natera* cases. *See, e.g.*, *Natera* case, Dkts. 54, 88, 93.

with the specifications of the Patents-in-Suit. As the specifications make clear, the patented methods utilize standard isolation techniques that do not specifically isolate cell-free fetal nucleic acids from cell-free maternal nucleic acids. Indeed, in every example provided in the specification, standard isolation techniques are used for isolating cell-free nucleic acids. *See, e.g.*, '277 Patent at 89:17–34 (stating that template DNA containing both free fetal and maternal nucleic acid "was isolated using the Qiagen Midi Kit"); 220:33–221:21; '720 Patent at 89:51–54, 211:38–63. None of these isolation techniques result in the isolation of cell-free fetal nucleic acid from everything else, including cell-free maternal nucleic acids. Because LabCorp's proposed construction would exclude every example in the specification of isolating free nucleic acids, the isolating terms cannot be construed to require "separating out free fetal nucleic acid ***from everything else***," and the Court should reject LabCorp's proposed constructions. *See Oatey*, 514 F.3d at 1276–77.

IV. "agent that [inhibits cell lysis to inhibit the lysis of cells/inhibits lysis of cells/impedes cell lysis] . . . wherein said agent is selected from the group consisting of membrane stabilizer, cross-linker, and cell lysis inhibitor" / "said sample comprises an agent that [impedes cell lysis/inhibits lysis of cells], if cells are present, and wherein said agent is selected from the group consisting of membrane stabilizer, cross-linker, and cell lysis inhibitor" ('277 Patent, Claims 55, 81; '720 Patent, Claim 1)[5]

Ravgen's Proposed Construction	LabCorp's Proposed Construction
plain and ordinary meaning	indefinite

This Court previously construed the agent terms as used in Claims 55 and 81 of the '277 Patent and Claim 1 of the '720 Patent to have their plain and ordinary meaning. *See PerkinElmer* case, Dkt. 78 at 2; *Natera* case, Dkt. 88 at 2, 93-1[6] at 2. Pursuant to the parties' agreement to forgo briefing on this term and rely on the prior briefing from the *PerkinElmer* and *Natera* cases, Ravgen

[5] These terms are referred to collectively herein as "the agent terms."

[6] The parties in the *Natera* case recently filed a Joint Motion To Enter Amended Claim Construction Order, proposing changes to the Court's original to reflect their understanding of the Court's intended rulings.

hereby incorporates by reference its claim construction briefing, including all exhibits, from those cases. *See PerkinElmer* case, Dkts. 50, 53, 58; *Natera* case, Dkts. 46, 55. Ravgen reserves the right to respond to any arguments LabCorp raises in its Responsive brief.

V. "formalin" ('277 Patent, Claims 60, 90-93, 132, 133)

Ravgen's Proposed Construction	LabCorp's Proposed Construction
plain and ordinary meaning	a stock solution of formaldehyde, usually 37% weight to volume

This Court previously construed the term "formalin" as used in Claims 60, 90-93, 132, 133 of the '277 Patent to have its plain and ordinary meaning. *See PerkinElmer* case, Dkt. 78 at 2. Pursuant to the parties' agreement to forgo briefing on this term and rely on the prior briefing from the *PerkinElmer* case, Ravgen hereby incorporates by reference its claim construction briefing, including all exhibits, from that case. *See PerkinElmer* case, Dkts. 50, 53, 58. Ravgen reserves the right to respond to any arguments LabCorp raises in its Responsive brief.

VI. "method for preparing a sample for analysis comprising isolating free fetal nucleic acid from the sample" ('277 Patent, Claim 81)[7]

Ravgen's Proposed Construction	LabCorp's Proposed Construction
plain and ordinary meaning	indefinite

Because the preparation term on its own, as well as read in light of the specification of the Patent-in-Suit, would inform, with reasonable certainty, a POSITA about the scope of that limitation, LabCorp cannot prove by clear and convincing evidence that this term is indefinite. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). The plain language of the preparation term is clear and the intrinsic record provides extensive guidance confirming its scope. Indeed, in LabCorp's *inter partes* review petition and accompanying declaration challenging

[7] This term is referred to herein as "the preparation term."

Claim 81 of the '277 Patent, LabCorp and its expert understood and applied this term according to its ordinary meanings, further evidencing that it is not indefinite. *See Canon, Inc. v. TCL Elecs. Holdings Ltd.*, No. 2:18-cv-00546-JRG, 2020 WL 2098197, at *39 (E.D. Tex. May 1, 2020); *see, e.g.*, *Lab'y Corp. of Am. Holdings v. Ravgen, Inc.*, IPR2021-00902, Paper 001 at 4 (PTAB May 3, 2021) ("[i]ndependent claim 81 recites a method for preparing a biological sample for analysis comprising isolating free fetal nucleic acid from the sample, wherein the sample includes an agent known to inhibit cell lysis."); *id.* at 9 ("the claim terms should be construed according to their ordinary and customary meaning"); *id.* at 20-21 (applying Claim 81 to alleged prior art references). Ignoring that the preparation term must be read through the lens of a POSITA, LabCorp attempts to render the claim indefinite. But LabCorp's theory conflicts with the plain reading of the claim and should therefore be rejected.

A. A POSITA Would Understand The Preparation Term Of Claim 81 With Reasonable Certainty

As explained by Dr. Brian Van Ness, a professor of genetics and cell biology with decades of experience working in a lab with biological samples, a POSITA would understand the scope of the preparation term based on its plain language. *See* Van Ness Decl.[8] ¶ 26. That plain language makes clear to a POSITA that the claim requires preparing a sample for analysis by isolating components of that sample. *Id.* ¶ 28. The claim includes a preamble that summarizes the method to be performed (preparing a sample for analysis) and a method step reciting the action to be performed on that sample (isolating free nucleic acid). *Id.* ¶ 29. Although the preamble recites that the sample is prepared for analysis, the claim does not require analysis of any sample. *Id.* ¶ 30.

[8] "Van Ness Decl." refers to the July 21, 2020 Declaration of Brian G. Van Ness, Ph.D., filed herewith.

This claim language is consistent with how POSITAs regularly engage in preparing samples in the lab—they refine collected samples to get components of that sample ready to analyze. *Id.* ¶ 31. In the context of preparing samples containing nucleic acids, that preparation often involves separating or removing certain components of the sample so that the components of interest (*e.g.*, the nucleic acids) can be analyzed more easily. *Id.* ¶ 32. Dependent Claim 85 of the '277 Patent, which requires "wherein the sample is blood," illustrates how the preparation term applies in the context of a particular sample type. That claim, which depends from Claim 81, includes "preparing [blood] for analysis comprising isolating free fetal nucleic acid from the [blood]." That plain language informs the POSITA exactly how to prepare the blood sample for analysis, by isolating free fetal nucleic acid from the blood. *Id.* ¶ 33.

The specification further illustrates the straightforward application of this term according to its plain and ordinary meaning. The specification includes an aspect of the invention wherein "the invention provides methods for preparing a sample for analysis that include isolating free nucleic acid from a sample that contains nucleic acid" and further wherein "the portion of the sample that is to be analyzed is the free nucleic acid, not the cellular portion." '277 Patent at 15:15-22; Van Ness Decl. ¶ 36. This confirms that, according to Claim 81 of the '277 Patent, a POSITA would prepare the original sample for analysis by isolating some components of the sample. The examples provided in the '277 Patent further highlight the straight forward application of the preparation term according to its plain meaning. For example, in Example 15, blood samples are collected (*see* '277 Patent at 219:54–220:32) and prepared for analysis by isolating plasma from the blood sample (*see* '277 Patent at 220:33–220:59), and then isolating DNA from the plasma (*see* '277 Patent at 220:61–221:21). Van Ness Decl. ¶ 37. In this

example, the blood sample is being prepared for analysis by isolating the DNA component of that blood sample. *Id.* ¶ 38.

B. LabCorps's Arguments That The Preparation Limitation Is Indefinite Lacks Merit.

LabCorp's argument that the preparation term is indefinite is premised on its own manufactured requirement that the entirety of the original (unmodified) sample ultimately be analyzed. That requirement finds no support in the claim language and is inconsistent with the ordinary use of the term in the art. As an initial matter, Claim 81 does not include any method steps requiring the analysis of any sample, let alone requiring the analysis of a particular sample. Nor does the preamble's recitation of "preparing a sample for analysis" require the performance of any analysis of any sample. *Id.* ¶ 30. Thus, Claim 81 does not require that a sample be analyzed at all.

Further, the ordinary meaning of "preparing a sample for analysis" does not limit any future analysis to the analysis of the entirety of an unmodified sample. According to Dr. Van Ness, in order to prepare a sample for analysis, a POSITA would regularly perform some action to the sample so as to get the sample ready for said analysis. Van Ness Decl. ¶ 31, 37-38, 40. The specification uses "sample" to describe many sample types, including blood samples containing free nucleic acid, as well as the plasma portion of blood samples containing free nucleic acid. *See, e.g.,* '277 Patent at 6:11-13, 41–45. Each of these samples requires some action taken to prepare them for analysis, including for example, isolating free nucleic acid in the sample. Van Ness Decl. ¶ 38, 40. Indeed, the examples provided in the specification of the '277 Patent require modification of the collected blood sample prior to any analysis being performed on components of those blood samples. *See, e.g.*, *id* at 219:39 –221:21; Van Ness Decl. ¶37.

LabCorp's attempt to not only add an analysis limitation into the claim, but to further

require that analysis only use all components of "the sample," contravenes the requirements of the claim and the tenets of claim construction. Thus, the Court should reject LabCorp's arguments and give the preparation term its plain and ordinary meaning.

VII. "said sample" ('277 Patent, Claim 88; '720 Patent, Claims 5, 6)

Ravgen's Proposed Construction	LabCorp's Proposed Construction
plain and ordinary meaning	indefinite

The dependent limitations regarding the biological sample used in the claimed methods of the '277 and '720 Patents alone—and read in light of the specifications of the Patents-in-Suit—would inform a POSITA about the scope and content of the sample with reasonable certainty. Because the scope of the claim is clear, LabCorp cannot prove by clear and convincing evidence that this term is indefinite.[9] *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). The plain language of the sample limitations fit well within the bounds of claim differentiation and are internally consistent. In fact, "the doctrine of claim differentiation, [which] presumes that dependent claims are 'of narrower scope than the independent claims from which they depend,'" (*Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357, 1371 (Fed. Cir. 2017) (quoting *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1242 (Fed. Cir. 2003)), contemplates the exact situation that LabCorp now claims renders the term "said sample" indefinite. Because LabCorp's

[9] Similar to the preparation term discussed above, LabCorp's argument that Claim 88 of the '277 Patent and Claims 5 and 6 of the '720 Patent are indefinite is belied by positions LabCorp has taken in *inter partes* review petitions challenging the validity of those same claims. In challenging each of those claims, LabCorp was able to apply its understanding of the meaning of the claim term "said sample" to the alleged prior art. *See Lab'y Corp of Am. Holdings v. Ravgen Inc.*, IPR2021-00902, Paper 001 at 28-29 (PTAB May 3, 2021); *Lab'y Corp. of Am. Holdings v. Ravgen, Inc.*, IPR2021-01026, Paper 001 at 29 (PTAB May 28, 2021). That LabCorp has already applied a plain and ordinary meaning to this term in related *inter partes* review proceedings supports Ravgen's construction. *See Canon*, 2020 WL 2098197, at *39.

theories are premised on a misreading the plain language of the claims and a misunderstanding of the biological properties of the claimed samples, those theories should be rejected.

A. A POSITA Would Understand The Sample Limitation With Reasonable Certainty

As explained by Dr. Van Ness, a POSITA would understand the scope of the sample limitations based on the plain language of "blood" and "obtained from plasma from said blood." *See* Van Ness Decl. ¶ 43. That plain language makes clear to a POSITA that a sample must not only be blood, but it must also be a particular type of blood sample: plasma, the liquid portion of unclotted blood in which cells may be suspended. *Id.* ¶ 46-47. In the broader claims, which recite "the sample is blood," the method includes (1) "isolating free fetal nucleic acid from the [blood] sample" for the '277 Patent or (2) "isolating free nucleic acid from a non-cellular fraction of a [blood] sample" for the '720 Patent. However, those broader claims do not dictate from which part of the blood the free nucleic acid is isolated as long as it is isolated from the blood generally ('277 Patent) or from a non-cellular fraction of the blood ('720 Patent). *See* '277 Patent at Claim 81; '720 Patent at Claim 1. On the other hand, Claim 88 of the ''277 Patent and Claim 6 of the '720 Patent, which depend from those broader claims, are narrower in that they specify a particular type of blood sample ("wherein the sample is obtained from the plasma of said blood"). For example, wherein the sample is obtained from the plasma of said blood, the sample is still a blood sample, but it is specifically obtained from the plasma portion of the blood. Van Ness Decl. ¶ 46, 53. From that plasma, a POSITA can isolate free nucleic acid in accordance with the claims. *Id.* ¶ 54. The plain language of the claims, thus, informs the POSITA of exactly the scope of "said sample" in the claims.

The specifications further illustrate the notion that, according to its plain and ordinary meaning, "said sample" obtained from plasma from said blood is simply a particular type of blood

sample. For example, the specifications explain that DNA can be "isolated from plasma or serum obtained from the blood." *See* '277 Patent at 26:62-64; '720 Patent at 28:12-14. While plasma means the liquid portion of unclotted blood, serum is the liquid portion of clotted blood. Van Ness Decl. ¶ 47. Therefore, the broader claims reciting "wherein the sample is blood" can include at least isolating free nucleic acid from plasma or serum, both of which are types of blood samples. For example, Claim 5 of the '720 Patent does not limit the sample beyond requiring that it be blood and therefore allows for the isolation of free nucleic acid from the non-cellular fraction of any blood sample (*e.g.*, either plasma or serum). By contrast, in Claim 6 of the '720 Patent, the blood sample must be obtained from plasma. Therefore, the specification confirms what a POSITA would understand: that the types of blood samples covered by Claim 5 of the '720 Patent and Claim 85 of the '277 Patent are broader than the types of blood samples (obtained from plasma) required by Claim 6 of the '720 Patent and Claim 88 of the '277 Patent. Van Ness Decl. ¶ 52-53.

B. LabCorp's Arguments That The Sample Limitation Is Indefinite Lacks Merit.

According to LabCorp, the term "said sample" as used in the claims is indefinite because (1) the term refers to said blood but says in a later claim that the sample is plasma obtained from blood, (*see* Ex. 4 at 66) and (2) "the antecedent basis for the term 'said sample' is blood and the claim recites 'plasma' as 'said sample'" (*id.* at 67). LabCorp's theory appears to be based on the incorrect notion that plasma is not blood. But LabCorp's premise that the sample cannot be both blood and obtained from the plasma of blood misunderstands those terms and injects confusion where none is present in the plain language. As explained by Dr. Van Ness, plasma is a component of blood. Van Ness Decl. ¶ 47. Specifically, plasma is the liquid component of unclotted blood, in which the cells and other components of blood may be suspended. *Id.*

Having one claim state that the sample is blood, followed by a dependent claim pointing to a specific part of the blood from which the blood sample is obtained is therefore entirely

internally consistent. There is nothing unclear about the requirement in Claim 6 of the '720 Patent and Claim 88 of the '277 Patent that the blood sample of those claims must have been obtained from the plasma portion of the blood. Accordingly, because "there is nothing about the claim term [] that is confusing[,] . . . the term requires no construction." *Pisony v. Commando Constr., Inc.*, No. W-17-cv-00055-ADA, 2019 WL 928406, at *5 (W.D. Tex. Jan. 23, 2019).

VIII. "non-cellular fraction" ('720 Patent, Claim 1)

Ravgen's Proposed Construction	LabCorp's Proposed Construction
plain and ordinary meaning	a separated portion substantially free of intact cells

This Court previously construed the term "non-cellular fraction" as used in Claim 1 of the '720 Patent to have its plain and ordinary meaning. *See PerkinElmer* case, Dkt. 78 at 2. Pursuant to the parties' agreement to forgo briefing on this term and rely on the prior briefing from the *PerkinElmer* case, Ravgen hereby incorporates by reference its claim construction briefing, including all exhibits, from that case. *See PerkinElmer* case, Dkts. 50, 53, 58. Ravgen reserves the right to respond to any arguments LabCorp raises in its Responsive brief, including any arguments related to extrinsic evidence not previously relied upon by any party in the *PerkinElmer* case.

CONCLUSION

For the foregoing reasons, Ravgen respectfully requests that the Court construe the disputed claim terms as proposed by Ravgen.

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By: /s/ *Kerri-Ann Limbeek* (*pro hac vice*)

Deron R. Dacus
State Bar No. 00790553
THE DACUS FIRM, P.C.
821 ESE Loop 323, Suite 430
Tyler, TX 75701
Phone: (903) 705-1117
Fax: (903) 581-2543
ddacus@dacusfirm.com

John M. Desmarais (*pro hac vice*)
Kerri-Ann Limbeek (*pro hac vice*)
Jamie L. Kringstein (*pro hac vice*)
Kyle G. Petrie *(pro hac vice*)
Joze Welsh (*pro hac vice*)
Jun Tong (*pro hac vice*)
Deborah J. Mariottini *(pro hac vice*)
Peter Zhu (*pro hac vice*)
DESMARAIS LLP
230 Park Avenue
New York, NY 10169
Telephone: 212-351-3400
Facsimile: 212-351-3401
jdesmarais@desmaraisllp.com
klimbeek@desmaraisllp.com
jkringstein@desmaraisllp.com
kpetrie@desmaraisllp.com
jwelsh@desmaraisllp.com
jtong@desmaraisllp.com
dmariottini@desmaraisllp.com
pzhu@desmaraisllp.com

Attorneys for Ravgen, Inc.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that all counsel of record who are deemed to have consented to electronic service are being served with a copy of this document via the Court's CM/ECF system on July 21, 2021.

Dated: July 21, 2021

/s/ *Kerri-Ann Limbeek*

Kerri-Ann Limbeek
E-mail: klimbeek@desmaraisllp.com
DESMARAIS LLP
230 Park Avenue
New York, NY 10169
Telephone: 212-351-3400
Facsimile: 212-351-3401